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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,354	12/22/2004	Robert J. Hariri	9516-059-999	6502
20583	7550	06/02/2008		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER BRISTOL, LYNN ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 06/02/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/511,354

**Applicant(s)**

HARIRI ET AL.

**Examiner**

LYNN BRISTOL

**Art Unit**

1643

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 27, 28 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 27, 28, 31-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 1-13, 27, 28, 31-36 are all the pending claims for this application.
2. Claims 25, 26, 29 and 30 were cancelled and Claims 1, 13, 27, 28 and 36 were amended in the Response of 3/5/08.
3. Claims 1-13, 27, 28, 31-36 are all the pending claims under examination.
4. Applicants amendments to the claims have necessitated new grounds for rejection. This action is FINAL.

**Withdrawal of Objections**

***Specification***

5. The objection to the specification is withdrawn for the following informalities:
  - a) The cross-reference to the priority documents has been amended to include the 371 application, PCT/US03/11578, filed 4/14/03.

**Withdrawal of Rejections**

***Claim Rejections - 35 USC § 112, second paragraph***

6. The rejection of Claims 1-12, 31 and 33-36 for the recitation "a plurality of stem cells" in Claim 1 is withdrawn in view of the amendment of Claim 1 to recite that the stem cells are "isolated human CD34- placental stem cells" and that "said placental stem cells are obtained from a human placenta that has been drained of cord blood and perfused to remove residual blood."

Applicants allege on the bottom of p. 6 of the Response of 3/5/08 that the term ““plurality” to mean two or more stem cells.”

The definition is not provided in the specification but the commercial, on-line Merriam-Webster dictionary defines the term as “a large number or quantity” (see attached copy of definition).

7. The rejection of Claims 1-13 and 25-33 in lacking antecedent basis for the limitation “said control level” in line 8 of Claim 1 and line 9 of Claim 13 is withdrawn in view of the amendment of Claims 1 and 13 to replace “control level” with “control amount.”

Applicants’ allegations on p. 7 of the Response of 3/5/08 are acknowledged.

8. The rejection of Claims 1-13 and 25-36 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps describing the relationship or correlation between the endothelial growth and the microvessel outgrowth from the stem cells in Claim 1 and the microvessel outgrowth from the vessel section in Claim 13 is moot for cancelled Claims 25, 26, 29 and 30 and withdrawn for the pending claims.

The amendment of Claims 1 and 13 to delete the recitation pertaining to “endothelial cells” obviates the rejection.

The rejection of Claims 1 and 13 for the recitation “for a time and under conditions in which endothelial cells grow” is withdrawn in view of the deletion of those portions of the phrase “for a time” and “endothelial cells grow”.

Applicants' allegations on p. 7 of the Response of 3/5/08 are acknowledged.

9. The rejection of Claim 3 for the recitation "a plurality of tumor cells" is withdrawn for the reasons set forth above under section 6.

10. The rejection of Claim 36 in lacking antecedent basis for the limitation "said stimulator of angiogenesis" is withdrawn in view of the amendment of the claim to depend from Claim 35.

***Claim Rejections - 35 USC § 102***

11. The rejection of Claims 1-9, 12, 29, 30, and 34-36 under 35 U.S.C. 102(e) as being anticipated by Drake et al. (WO 01/63281; published 8/30/01; priority to 2/23/00; cited in the IDS of 10/4/07) is withdrawn.

Applicants' amendment of Claim 1 to recite that the method requires a starting population of a "plurality of isolated human CD34- placental stem cells" and where the stem cells "are obtained from a human placenta that has been drained of cord blood and perfused to remove residual blood" distinguishes the method from Drake.

Applicants' allegations on pp. 7-8 of the Response of 3/5/08 are acknowledged.

***Claim Rejections - 35 USC § 103***

12. The rejection of Claims 1 and 36 under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (WO 01/63281; published 8/30/01; priority to 2/23/00; cited in the IDS

of 10/4/07) in view of Fox et al. (J. Pathol. 179:232-237 (1996); cited in the IDS of 1/27/05) is withdrawn.

Applicants' amendment of Claim 1 to recite that the method requires a starting population of a "plurality of isolated human CD34- placental stem cells" and where the stem cells "are obtained from a human placenta that has been drained of cord blood and perfused to remove residual blood" distinguishes the method from Drake.

Applicants' allegations on p. 9 of the Response of 3/5/08 are acknowledged.

13. The rejection of Claims 1, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (WO 01/63281; published 8/30/01; priority to 2/23/00; cited in the IDS of 10/4/07) as applied to claim 1 above, and further in view of Montesano et al. (J. Cell. Physiol. 132(3): 509-516 (1987); cited in the IDS of 1/27/05) is withdrawn.

Applicants' amendment of Claim 1 to recite that the method requires a starting population of a "plurality of isolated human CD34- placental stem cells" and where the stem cells "are obtained from a human placenta that has been drained of cord blood and perfused to remove residual blood" distinguishes the method from Drake.

Applicants' allegations on pp. 9-10 of the Response of 3/5/08 are acknowledged.

14. The rejection of Claims 1 and 5 under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (WO 01/63281; published 8/30/01; priority to 2/23/00; cited in the IDS

Art Unit: 1643

of 10/4/07) as applied to claim 1 above, and further in view of Crouse et al. (Kroc Found. Ser. 18:211-231 (1984)) is withdrawn.

Applicants' amendment of Claim 1 to recite that the method requires a starting population of a "plurality of isolated human CD34- placental stem cells" and where the stem cells "are obtained from a human placenta that has been drained of cord blood and perfused to remove residual blood" distinguishes the method from Drake.

Applicants' allegations on pp. 11-12 of the Response of 3/5/08 are acknowledged.

15. The rejection of Claims 1, 2 and 33 under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (WO 01/63281; published 8/30/01; priority to 2/23/00; cited in the IDS of 10/4/07) as applied to claims 1 and 2 above, and further in view of Merrick et al. (Transplantation 62(8): 1085-1089 (1996)) is withdrawn.

Applicants' amendment of Claim 1 to recite that the method requires a starting population of a "plurality of isolated human CD34- placental stem cells" and where the stem cells "are obtained from a human placenta that has been drained of cord blood and perfused to remove residual blood" distinguishes the method from Drake.

Applicants' allegations on p. 12 of the Response of 3/5/08 are acknowledged.

16. The rejection of Claims 25 and 26 under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (WO 01/63281; published 8/30/01; priority to 2/23/00; cited in the IDS

Art Unit: 1643

of 10/4/07) as applied to claim 1 above, and further in view of Zygmunt (Early Pregnancy 5(1):72-73 (Jan 2001)) is withdrawn and moot for the cancelled claims.

**Rejections Maintained**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

17. The rejection of Claim 13 under 35 U.S.C. 102(e) as being anticipated by Drake et al. (WO 01/63281; published 8/30/01; priority to 2/23/00; cited in the IDS of 10/4/07) is maintained.

Claim 13 is interpreted as being drawn to a method for identifying a modulator of angiogenesis comprising culturing a vessel section in the presence of a plurality of tumor cells and a test compound under conditions that enable microvessel outgrowth from the section and comparing microvessel outgrowth from the vessel between the test and a control sample.



Applicants' allegations on the top of p. 8 of the Response of 3/5/08 have been considered but are not found persuasive. Applicants allege that Drake does not disclose the use of tumor cells in the assays as presently claimed, and that Example 10 in Drake is a prophetic example directed only to an assay to determine the effect of tumor cells on angiogenesis and vasculogenesis in an irradiated mouse.

The examiner submits that Drake discloses methods for assessing the potency of a candidate agent that promotes or inhibits neovascularization. For example, potency of an agent can be determined by measuring tumor growth; an amount that slows or prevents tumor growth would be a therapeutically effective amount of an agent that inhibits neovascularization (p. 15, lines 17-20); Drake explains that the methods for screening for angiogenesis would involve contacting a substrate such as a culture or organ or tumor with the agent, where the agent is added to the culture medium (i.e., "by changing the medium to a medium that contains the agent") or by adding the agent to the extracellular fluid in vivo (p. 12, lines 25-32). Thus implicit to Drakes disclosure is the fundamental understanding that a tumor would contain microvessels, which when contacted by the test agent, would either stimulate or inhibit microvessel outgrowth, thus effecting tumor growth. Drake further teaches in the same paragraph that vasculature can be imaged using techniques known in the art, including, for example, angiography (fluorescein angiography, radio-angiography, or indocyanine grene angiography). Further, Example 10 of Drake is provided as an example of an in vivo model for examining angiogenesis in breast tumors and on which the screening methods for test agents could be readily practiced in vivo. Drakes' disclosure encompasses explanted

Art Unit: 1643

tissues from tumors that would contain a vessel(s) and a plurality of tumor cells and thus the disclosure of Drake is maintained as reading on the method of Claim 13.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The rejection of Claims 1, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (WO 01/63281; published 8/30/01; priority to 2/23/00; cited in the IDS of 10/4/07) Drake is withdrawn above as pertaining to claim 1 in view of Zygmunt (Early Pregnancy 5(1):72-73 (Jan 2001)) is maintained.

For purposes of review, the rejection from the Office Action of 12/5/07 is set forth as follows:

"The claimed method was *prima facie* obvious over Drake and Zygmunt.

The interpretation of Drake is discussed *supra*. Drake discloses using allantoic explants in assaying for stem cell differentiation into endothelial cell precursors for formation of vessels structures and various other organs but does not disclose using placental-derived stem cells as endothelial cell precursors, which does Zygmunt.

Zygmunt discloses that placental vascularization occurs by vasculogenesis and angiogenesis and is mediated by endothelial progenitor cells present in the developing primitive organ. Zygmunt does not describe the phenotype of the placental stem cells for endothelial progenitors, but one of skill in the art would envisage that the endogenous placental stem cells inherently possess the phenotype of CD34- (Claim 26), or Oct4+, SSEA3- and SSEA4- (Claim 27) or CD10+, CD29+, CD44+, Cd54+, CD90+, SH2+, SH3+ SH4+, OCT4+, CD34-, CD38-, CD45-, SSEA3- and SSEA4- (Claim 28), where the markers were already known in the art and the technology (PCR primers for detecting the respective mRNA or antibodies specific for each cell marker for FACS sorting) for separating cells with the phenotype was well within the ordinary skill of the artisan at the time of the invention. ("The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property, which is inherently present in the prior art does not necessarily make the claim patentable. In re

Art Unit: 1643

Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1997)).

One skilled in the art would have been motivated and reasonably assured of success in having produced the method for identifying a modulator of angiogenesis using placental-derived stem cells comprising endothelial progenitors based on the combined disclosures of Drake and Zygmunt. Drake discloses the culture conditions for assaying angiogenesis modulators (agonist and antagonist) which effect allantoic-derived stem cell differentiation into endothelial cells and Zygmunt discloses that placenta also contains endothelial progenitor stem cells critical for forming blood vessels. One skilled in the art could have readily modified the culture conditions of Drake by introducing the placental-derived stem cells disclosed in Zygmunt and having the inherent phenotype and/or selecting for a phenotype of CD34-, or Oct-4+, SSEA3- and SSEA4-, or CD10+, CD29+, CD44+, Cd54+, CD90+, SH2+, SH3+ SH4+, OCT4+, CD34-, CD38-, CD45-, SSEA3- and SSEA4- because Zygmunt discloses that the placenta is rich in endothelial cell progenitors capable of forming vessel beds. One skilled in the art would have been reasonably assured of success in having introduced the placental-derived stem cells into the culture assay system of Drake because the stem cells were recognized as being endogenous cells known to be essential for differentiation into microvessels."

Applicants' allegations on pp. 10-11 of the Response of 3/5/08 have been considered but are not found persuasive. Applicants allege that the Examiner has not cited any reference authority to support the inherency rejection that Zygmunt's placental precursor cells would be inherently CD34- much less that the placental precursors would have the phenotype for Oct-4+, SSEA3- and SSEA4- (Claim 27) or CD10+, CD29+, CD44+, Cd54+, CD90+, SH2+, SH3+ SH4+, OCT4+, CD34-, CD38-, CD45-, SSEA3- and SSEA4- (Claim 28). Applicants further allege that the angioblasts of Zygmunt would be CD34+ as evidenced by Urbich and Dimmler (Circulation Res. 95:343-353 (2004)), where at p. 344, Col. 1, Urbich teaches "that angioblasts and hemangioblasts" are CD34+.

The examiner respectfully submits that the Urbich reference supplied by Applicants supports and substantiates the examiner's original position that precursor cells with a CD34- phenotype would give rise to endothelial progenitor cells. Urbich specifically teaches "There is increasing evidence that myeloid cells can give rise to endothelial cells as well. Specifically, CD14+/CD34- myeloid cells can co-express endothelial markers and form tube-like structures ex vivo" (p. 344, Col. 1, ¶13). Thus

Art Unit: 1643

contrary to Applicants assertion, a precursor or stem cell having the CD34- phenotype was known in the art to give rise to endothelial cells. Thus absent a showing to the contrary, a CD34- stem cell further having the phenotype for Oct-4+, SSEA3- and SSEA4- or CD10+, CD29+, CD44+, Cd54+, CD90+, SH2+, SH3+ SH4+, OCT4+, CD38-, CD45-, SSEA3- and SSEA4- would have been inherent to the placental precursors described by Zygmunt.

**New Grounds for Objection**

***Claim Objections***

19Claims 1 and 13 are objected to because of the following informalities: the preamble of both claims 1 and 13 appears to recite a typographical error for the term "angiogenesis". Appropriate correction is required.

**New Grounds for Rejection**

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

20. Claims 13 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 13 and 32 are indefinite because the relationship between the plurality of tumor cells and the microvessel outgrowth from the vessel section is unclear. Do the tumor cells effect or contribute to the conditions which allow microvessel outgrowth from the vessel section, and does the control culture also require the presence of tumor cells to observe a basal level or "control amount" of microvessel outgrowth?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

***Enablement***

21. Claims 1-12, 27, 28, 31, and 33-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identifying angiogenesis or vasogenesis modulators in a method comprising adding the modulator to isolated human CD34- placental stem cells in the presence of cultured umbilical cord blood vessel rings to observe changes in microvessel outgrowth from the vessels, does not reasonably provide enablement for a method of scoring microvessel outgrowth from the CD34- stem cells per se. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). They include the nature of the invention, the state of the prior art, the relative skill of those in

Art Unit: 1643

the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability of the art, the breadth of the claims, the quantity of experimentation which would be required in order to use the invention as claimed.

Nature of the Invention/ Skill in the Art

Claims 1-12, 27, 28, 31, and 33-36 are broadly drawn to a method for identifying a modulator of angiogenesis or vasogenesis in a method comprising culturing a plurality of isolated human CD34- placental stem cells under conditions in which microvessel outgrowth from the placental stem cells occurs and where an amount of microvessel outgrowth from the stem cells in the presence of the modulator is compared to a control amount of microvessel outgrowth. The claims are interpreted as the CD34- placental stem cells per se being able to actually produce or differentiate into microvessels.

The relative skill in the art required to practice the invention is a clinical technician with a background in cell culture and microscopy.

Disclosure in the Specification/ Undue Experimentation/ Unpredictability

The specification does not disclose that the CD34- placental stem cells isolated from human placenta drained of cord blood and perfused to remove residual blood, and placed under any culture conditions in vitro, would per se give rise to or produce microvessels. The specification discloses the following examples using the CD34- placental stem cells or human umbilical vessel sections and the results observed from those studies:

Example 6.1/6.2 (working): the stem cells were cultured alone in vitro and shown to develop tube-like structures and to express different markers. Addition of modulators effected expression of different markers (Table 2) and the branching or bifurcation of the cells (Table 4);

Example 6.3.2 (working): human umbilical cord vessel rings were cultured in the presence of modulators to compare microvessel outgrowth (Table 6);

Example 6.4 (prophetic): vessel rings and stem cells are co-cultured in the presence of modulators and examined for angiogenesis vis-à-vis vessel outgrowth; and

Example 6.5 (prophetic): vessel rings and tumor cells are co-cultured in the presence of modulators.

Significantly, nowhere in the specification have applicants demonstrated that the CD34- placental stem cells would actually produce or differentiate into microvessels. The closest demonstration of a structural change is the tube formation in Example 6.1 and the branching form in Example 6.2.

According to Urbich et al. (Circulation Res. 95:343-353 (2004)) the ordinary artisan could only predict that CD14+/CD34- myeloid cells can co-express endothelial markers and form tube-like structures *ex vivo*" (p. 344, Col. 1, ¶13).

Thus Applicants own specification is not enabling for its explicit or implicit disclosure for the isolation conditions or the culture conditions that would allow microvessel outgrowth to occur from the stem cells in vitro. The ordinary artisan must be able to discriminate between the effect of the test compound on microvessel outgrowth and the general ability of the stem cells to differentiate into or produce the microvessels

in vitro. The conditions that allow microvessel outgrowth from the stem cells to occur is seemingly critical and even rate limiting insofar as achieving the method endpoint, namely, identifying a modulator of angiogenesis or vasogenesis based on the outgrowth of microvessels from the stem cells. It is unpredictable that the ordinary artisan could even culture the CD34- stem cells and expect to observe microvessel outgrowth occurring from the cells themselves. The ordinary artisan would be required to perform undue trial and error experimentation to identify the culture conditions that would permit microvessel outgrowth for the isolated stem population to occur based on the written description of the specification alone.

### ***Conclusion***

22. No claims are allowed.
23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



Art Unit: 1643

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/David J Blanchard/  
Primary Examiner, Art Unit 1643